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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Docket No. 2006N-0065

May 11th 2006 Public Workshop on Emerging Clostridial Disease Comments

Comments Submitted on Behalf of Planned Parenthood Federation of America
by Dr. Vanessa Cullins

I am Dr. Vanessa Cullins, Vice President Medical Affairs of Planned Parenthood Federation of America. Planned Parenthood is the largest and most trusted provider of family planning services in the United States. Each year our affiliates, which are located in every state and the District of Columbia, serve approximately 3 million women and men at more than 850 health centers.

At Planned Parenthood, our highest priority is the health and safety of our patients. For this reason, Planned Parenthood commends the FDA, CDC and the National Institute of Allergy and Infectious Diseases for convening this meeting to address the important subject of emerging *C. difficile* and *C. sordellii* infections. Planned Parenthood agrees that it is crucial to create a research agenda and to learn more about these organisms, and the incidence, prevention and successful treatment of these infections.

In furtherance of these efforts, Planned Parenthood would like formally to offer at this time any assistance it can provide in carrying out the research agenda that emerges from this important meeting. Planned Parenthood is aware that *C. sordellii* sepsis has led to mortality among pregnant women. Planned Parenthood provides care to women through early detection of pregnancy, prenatal care, and abortion care. Throughout this country, we serve 2.7 million women each year at our health care centers. In collaboration with academic research institutions, many of our health care centers have participated in research studies. Planned Parenthood's multi-center clinical trial network has developed standard operating procedures for research which include training of research personnel on "Good Clinical Practice" for FDA-regulated trials. Please do not hesitate to contact me for our assistance in executing the research agenda that is being planned.

Once again, on behalf of Planned Parenthood Federation of America and our millions of clients and supporters, I wish to thank you for working together in an effort to find answers to the troubling public health questions posed by these Clostridial strains.



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